## REMARKS

Claims 10-20 are rejected under 35 USC §101 because the claimed invention is not supported by a specific asserted utility or well-established utility. These claims have been canceled.

Furthermore, Applicant respectfully disagrees. As the Examiner has noted, the specification teaches that the claimed sequences express themselves in diseased prostate tissue and, in Figure 3B, normal prostate tissues. The specification teaches that the claimed gene products express themselves more abundantly in prostate tissue than any other tissue, thereby establishing that prostate tissue is the host tissue of the claimed gene products.

Several assays utilizing the overexpression of tissue-specific gene products have been established in the art. The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

It is well known in the art that gene products that are expressed in a host tissue but not in other tissue can be used to indicate disease when they are found to be overexpressed in tissue outside their host tissue (e.g., CEA, PSA). Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case prostate tissue) into other areas of the body, such as blood. These examples demonstrate that presence of the claimed gene products outside normal host tissue serves as a diagnostic indicator that the host tissue is in a diseased state. Thus, the correlation to disease states of tissue-specific gene products such as those claimed in the present invention are established in the art. Because the claims should be analyzed in light of the teachings of the prior art and well-known techniques of immunohistochemistry for assessing overexpression are incorporated into the

specification, Applicant asserts that the examples and methods disclosed in the specification are useful for detecting, at the least, prostate diseases that may be detected using gene markers and related gene marker technology. Applicant respectfully submits that new claims 21-31 are now in a condition for allowance and requests that this rejection be withdrawn.

The Examiner further states that claims 18 and 20 recite "a composition of matter comprising a PS112 polynucleotide" and a "gene" respectively and thus read on non-statutory subject matter. These claims have been canceled. The Examiner states that the addition of the word "isolated" or "purified" would obviate this rejection. Applicant thanks Examiner for this clarification. New claims 21-31 include "purified" language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-20 are rejected under 35 USC §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. These claims have been canceled. Moreover, Applicant asserts that in light of the above amendments and remarks, the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-19 are rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been canceled.

The Examiner states that it is not clear what the term "PS112" is. Applicant respectfully disagrees. "PS112" is clearly defined in the specification at page 9, line 18 as a designation for a gene. Applicant respectfully reminds Examiner that an applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. Where an explicit definition is provided by the applicant for a term, for example at page 9, line 18 of the instant specification, that definition will control interpretation of the term as it is used in the claim. However, in an effort to expedite prosecution, claims 10-20 have been canceled and new claims 21-31 do

not include "PS112" language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

The Examiner further states that it is not clear to what the term "at least 50% identity" refers. Applicant respectfully disagrees. The claims may be interpreted in light of the specification, which defines the term "identity" and provides descriptions of "percent identity" at page 10. However, in an effort to expedite prosecution, claims 10-20 have been canceled and new claims 21-31 do not include "percent identity" language. Furthermore, new claims 21-31 encompass degenerate coding sequences thereof. The degeneracy of the genetic code is a concept that is well-known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as "the fact that most amino acids are specified by more than one nucleotide sequence or codon." Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-20 are rejected under 35 USC §102(b) as being anticipated by Matsubara et al. or Hillier et al. or Hudson et al. Matsubara et al. teaches a polynucleotide sequence that is 100% identical to SEQ ID NO:9 at positions 1-116. Hillier et al. teaches a polynucleotide sequence that is 100% identical to SEQ ID NO:9 at positions 1-412. Hudson et al. teaches a polynucleotide sequence that is 100% identical to SEQ ID NO:9 at positions 1-271. These claims have been cancelled. New claims 21-31 do not include SEQ ID NO:9. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,919,638. The Examiner states that the claims are both drawn to a polynucleotide of SEQ ID NO:9 and method making said nucleotide. These claims have been cancelled. New claims 21-31 do not include SEQ ID NO:9. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.


## CONCLUSION

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraws all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,
Cohen, *et al.*

ABBOTT LABORATORIES
D-0377/AP6D-2
100 Abbott Park Road
Abbott Park, Illinois 60064-6050
Phone: (847) 935-7550
Fax: (847) 938-2623

CARDINAL LAW GROUP
1603 Orrington Avenue
Suite 2000
Evanston, Illinois 60201
Phone: (847) 905-7111
Fax: (847) 905-7113

Mimi C. Goller
Registration No. 39,046
Attorney for Applicants

Ruth Pe Palileo
Registration No. 44,277
Agent for Applicants